9. 510(k) SUMMARY

APR - 9 2002

Submitted By:
Mark Bleyer, President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355

Device:

Trade Name:	STRATASIS™ Sling Kit
Common/Usual Name:	Surgical Mesh, Urethral Sling
Proposed Classification Name:	Surgical Mesh (PAG)

Intended Use:
The STRATASIS™ Sling Kit is a sterile, single-use device intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Predicate Devices:
The STRATASIS™ Sling Kit is similar in terms of substantial equivalence to the following predicate devices: SURGISIS Sling (K992159) manufactured by Cook Biotech Incorporated; the SIS Hernia Repair Device (K974540) manufactured by Cook Biotech Incorporated, and Tension Free Vaginal Tape (K974098) marketed by GYNECARE.

Device Description:
The STRATASIS™ Sling Kit is composed of a strip of SIS material with TEVDEK® suture attached to each end. Two stainless steel ligature carriers are also included.

Substantial Equivalence:
The STRATASIS™ Sling Kit is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The STRATASIS™ Sling Kit was subjected to a panel of tests to assess biocompatibility, disinfection, and performance characteristics. The STRATASIS™ Sling Kit met the requirements of all tests.

Conclusions Drawn from Tests:
The STRATASIS™ Sling Kit is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Mark Bleyer
President
Cook Biotech, Inc.
3055 Kent Avenue
WEST LAFAYETTE IN 47906

SEP 28 2012

Re: K020654
Trade/Device Name: STRATASIS™ Sling Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAG
Dated: February 27, 2002
Received: February 28, 2002

Dear Mr. Bleyer:

This letter corrects our substantially equivalent letter of April 9, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

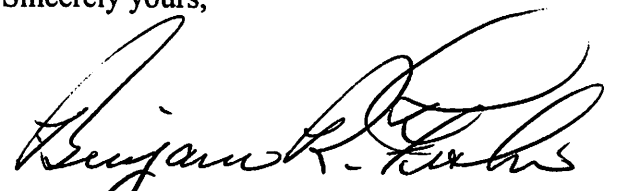
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020654

Device Name: STRATASIS™ Sling Kit

Indications For Use:

The STRATASIS™ Sling Kit is a sterile, single-use device intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020654

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)